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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,433	09/01/2000	Zuzana Kossaczka	2026-4298US	5517

27123 7590 08/16/2002
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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/16/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/653,433

Applicant(s)

Kossaczka et al

Examiner

Partner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 6, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5, 12, 14, and 16-23 is/are pending in the application.
- 4a) Of the above, claim(s) 16-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 12, and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1, 3-5, 12, 14, and 16-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 2,6-11,13 and 15 have been canceled.

Claims 1, 3-5,12,14 and new claims 16-23 are pending.

Amended claims 1, 3-5,12, and 14 are under consideration.

New Claims 16-23 are withdrawn from consideration as drawn to species of invention not previously considered.

Election/Restriction

1. Newly submitted claims 16-23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The previously examined claims were directed to the administration of a composition to any human, and the newly submitted claims are directed to the administration of the composition to humans of specific ages: 2-3 years old, 4-5 years old, 5-14 years old and adults.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-23 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Rejections Withdrawn

2. Claims 1-2, 5 and 12-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Szu et al (December 8, 1997, different inventive entity), in light of the "Katz" Declaration defining the inventorship of the instant specification and removing Szu et al (1997) as not being applicable prior art.

Rejections Maintained

3. Claim 14 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 44 of U.S. Patent No. (US Pat. 5,738,855). Although the conflicting claims are not identical, they are not patentably distinct from each other because the now claimed Vi antigen may be obtained from any source as long as it is characterized as S.typhi Vi antigen, and the allowed claims recite a species of Vi antigen that is synthetic, or immunologically equivalent obtained from a plant or fruit. A genus claim is obvious over a species.

4. Claims 1, 3-5, 12, and 14 rejected under 35 U.S.C. 102(e) as being anticipated by Szu et al (Filing date: October 17, 1994) for reasons of record in paper number 13, paragraph 6.

Response to Arguments

5. The rejection of claim 14 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 44 of U.S. Patent No. (US Pat. 5,738,855) is asserted to have been obviated through the cancellation of claims 2 and 13, and amendment of

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claim 14 to recite the phrase “derived from *S.typhi*” and asserting that the disclosure of Szu et al does not teach a Vi antigen derived from *S.typhi*, and the polysaccharide of *S.typhi* has an N-acetyl group that the fruit or plant polysaccharide does not.

6. It is the position of the examiner that the instantly claimed Vi antigen “derived from *S.typhi*” is not limited to only the naturally occurring structure, but includes polysaccharide derived from *S.typhi* Vi polysaccharide. While the genus of polysaccharides “derived from *S.typhi*” includes the native polysaccharide, it also includes derivatives of the *S.typhi* Vi polysaccharide which could include synthetic Vi antigens with or without the N-acetyl group (the species of ‘855, Szu et al, col. 2, lines 62-63; immunological identity claim 40).

With respect to the presence or absence of the asserted structural difference between the *S.typhi* Vi polysaccharide derived from *S.typhi* that would include an N-acetyl group, it is the position of the examiner that the claims do not require the presence or absence of an N-acetyl group in the Vi antigen of the instant claims.

The synthetic saccharide (see claim 35) of Szu et al ‘855, includes a synthetically synthesized Vi antigen that could include the N-acetyl group of the native Vi polysaccharide because the immunogenic Vi epitope is defined to include this structure. (see Szu et al, ‘855, col.2, lines 62-63). Additionally a Vi-rEPA conjugate was made and disclosed at Szu et al, col. 10, lines 30-31, Example 1. Applicant’s arguments are not commensurate in scope with the instantly claimed invention. The instant claims still recite a genus that the species of the prior art

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anticipates. A genus claim is obvious over a species. Filing of an effective terminal disclaimer could obviate this rejection.

7. The rejection of claims 1, 3-5, 12, and 14 under 35 U.S.C. 102(e) as being anticipated by Szu et al (October 17, 1994) is traversed through pointing to Table 2, claim 14, Example 7 and claim 49 of Szu et al and concludes that Szu et al does not immunize with “a Vi polysaccharide derived from *S.typhi* linked to rEPA via an adipic acid dehydrazide linker, and the O-acetylated pectin antigen is asserted to lack the N-acetyl group of *S.typhi* Vi polysaccharide.

8. It is the position of the examiner that the instantly claimed invention recites a genus of polysaccharides derived from *S.typhi* Vi polysaccharide.

The claim limitations recite the process step of “derived” *S.typhi* Vi polysaccharide, which would include synthetic Vi antigens with or without the N-acetyl group. The species of ‘855, Szu et al, is defined to be a synthetic antigen that comprises the antigenicity and immunogenicity of the Vi antigen (Szu et al, ‘855, col. 2, lines 62-63) and would evidence immunological identity (see Szu et al, defined in the specification and recite in claim 40).

With respect to the presence or absence of the asserted structural difference between the *S.typhi* Vi polysaccharide derived from *S.typhi* that would include an N-acetyl group, it is the position of the examiner that the claims do not require the presence or absence of an N-acetyl group in the Vi antigen of the instant claims.

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A Vi polysaccharide derived from *S.typhi* could comprise or not comprise the asserted structural component of an N-acetyl group as long as the polysaccharide derivative functions to induce an antibody directed to the Vi polysaccharide antigen.

The instantly amended claims define a genus of Vi polysaccharides that includes any derivatives of the Vi polysaccharide that will induce protective antibodies directed against the Vi polysaccharide antigen.

The synthetic saccharide (see claim 35) of Szu et al '855, includes a synthetically synthesized Vi antigen (see Table 2, col. 14, line 45; claims 40 and 49) that would include the N-acetyl group of the native Vi polysaccharide because the immunogenic Vi epitope is defined to include this structure. (see Szu et al, '855, col.2, lines 62-63). Additionally a Vi-rEPA conjugate was made and disclosed at Szu et al, col. 10, lines 30-31, Example 1.

Applicant's arguments are not commensurate in scope with the instantly claimed invention. Szu et al covalently linked to *Pseudomonas aeruginosa* recombinant exoprotein a (see claim 44) through a carboxylic acid dihydrazide linker (see claim 14), wherein the linker is identified by the abbreviation ADH to *S.typhi* Vi polysaccharide or a derivative of Vi polysaccharide.

The species of the prior art anticipates the instantly claimed genus of methods and compositions.

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Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 13, 2002

LS
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